

The Amendments to the Claims

The Amendments to the Claims

Claims 13-18 have been canceled as being drawn to a non-elected invention. Applicants reserve the right to pursue any canceled subject matter in a continuation, continuation-in-part, divisional, or other application. Cancellation of any subject matter should not be construed as abandonment of that subject matter. Claims 1 and 19 have been amended to recite "expressed in the living organism" rather than "expressed in a living organism"; "or" rather than "and" with respect to transient and stable gene expression; "tissue of a living organism" rather than "tissue of living organisms"; and "administering...using a jet injector" rather than "administering...through a jet injector technique". Claim 5 has been amended to recite the singular form of "components", "signals", and "sequences", and to recite the word "coding" instead of "coating". Claim 6 has been amended to remove the phrase "such as" and the subsequent limitations. In claim 7 the word "cites" has been amended to "sites". In claim 11 the period after "3 cm" has been removed, resulting in a lower case "d" for the word "distant". Claims 22 and 23 have been added and are supported in the specification by, for example, page 7, lines 15-21.

No new matter has been added by way of these amendments. Separate documents setting forth the precise changes to the specification and claims, as well as the text of all pending claims, are enclosed herewith.

Discussion of Rejection under 35 U.S.C. § 112, first paragraph

Claims 1-12 and 19-21 have been rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking enablement. The Office agrees that the claimed invention is enabled for methods of gene transfer for non-therapeutic purposes and for genetic immunization. The Office, however, alleges that the specification does not enable methods of gene therapy embodied in groups formerly identified as "(a)", "(b)", "(c)", and "(j)", or for the generation of a transgenic organism as in "(e)". This rejection is traversed for the reasons set forth below.

In order to advance prosecution, and not in acquiescence of the rejection, Applicants have amended claim 2, so that it no longer recites "gene therapy" as a method of use relating to claim 1. This amendment is believed to render the rejection moot with respect to (c).

The Office also alleges that the ablation of cells, as recited in groups "(a)" and "(b)" is not enabled by the specification. Applicants respectfully submit that cellular ablation is nothing more than destruction of cells. As such, the issues that the Office has raised with respect to gene therapy do not apply. Furthermore, the specification evidences the successful introduction of nucleic acids to somatic tissue via jet injection by way of the CAT and β -gal

gene delivery and expression data. The delivery of apoptosis or toxin genes to ablate diseased cells using the same methods is taught in the specification at, for example, page 15, line 12. Thus, the mere substitution of an apoptosis or toxic gene for the CAT or β -gal gene would not involve undue experimentation. Therefore, one of ordinary skill in the art is in fact, enabled to practice the claimed invention to the full scope of the claims.

The Office alleges that the specification does not enable a method of inducing wound healing since no actual showing of successful treatment is disclosed. Applicants submit that the group formerly identified as "(j)" (claim 2), now group "(i)", does not assert a therapeutic use as defined by the Office. Group "(i)" recites a method for "inducing" healing, not a method for healing. The Merriam-Webster Dictionary Online defines "inducing" as *bringing about by stimulation*. Therefore, the specification need only enable a method to stimulate healing. As such, the incorporation of exogenous DNA via jet injection will elicit an immune response, which in turn, will induce healing. Thus, the disclosure of the instant application enables group "(i)".

Lastly, with respect to § 112, first paragraph, the Office alleges that the specification does not enable a method to create transgenic organisms as recited in group "(e)". "Transgenic" has been amended to "chimeric" as suggested by the Office. This amendment is believed to render the rejection moot with respect to (e).

In view of the foregoing, Applicants submit that claims 1-12 and 19-21 are enabled by the specification. Accordingly, Applicants respectfully request withdrawal of the rejection under Section 112, first paragraph.

Discussion of Rejection under 35 U.S.C. § 112, second paragraph

Claims 1-12 and 19-21 have been rejected under Section 112, second paragraph, as allegedly indefinite for failing to point out particularly and claim distinctly the subject matter of the invention. The rejection is traversed for the reasons set forth below.

In order to expedite prosecution of this application and not in acquiescence of the rejection, the claims have been amended to incorporate most of the Office's suggestions as set forth in the recent Office Action. The amendments are directed to correcting obvious typographical and grammatical errors as well as replacing ambiguous terms with clear language. For example, claims 1 and 19 have been amended to recite "expressed in the living organism" rather than "expressed in a living organism"; "or" rather than "and" with respect to transient and stable gene expression; "tissue of a living organism" rather than "tissue of living organisms"; and "administering...using a jet injector" rather than "administering...through a jet injector technique".

Additionally, Claim 2 has been amended to recite "chimeric" instead of "transgenic". Claim 5 has been amended to recite the singular form of "components", "signals", and "sequences", and to recite the word "coding" instead of "coating". Claim 6 has been amended to remove the phrase "such as" and the subsequent limitations. Those limitations can now be found in newly added dependent claims 22 and 23. Claim 2 has been amended to eliminate specifically the word "bioreactor". Lastly, in claim 7 the word "cites" was amended to "sites", and in claim 11 the period after "3 cm" was removed, resulting in a lower case "D" for the word "distant".

Not all suggestions made by the Office were incorporated in the amended claims. For instance, the Office alleges that claim 10 is not clear when reciting "a hybrid gene selected from the group consisting of" several pairs of genes. Applicants point out that claim 10 is written in an acceptable form, known as a Markush grouping. See M.P.E.P § 2173.05(h). Thus, this claim format is clear and not indefinite.

The Office alleges that in claims 5 and 6 the term "specific" implies some limitation, which the term modifies, but the limitation is not apparent. The Federal Circuit has held, that "[t]he test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification." See *Miles Labs., Inc., v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1994). Applicants point out that in claims 5 and 6 the term "specific" modifies the objective "manner" of expression that would result from a single permutation of the identified, variable elements. Therefore, one ordinarily skilled in the art would understand that each combination of elements would lead to a specific manner of expression relative to every other potential variation.

In claim 2, the Office alleges as indefinite the phrase "further involving the steps of a member selected from" the recited group. Applicants point out that "the steps" refer to method steps known by those of ordinary skill in the art. See Molecular Biology of the Cell, Darnell; pg. 181-194, 247-248, 828-839, 958-959 (1986). The method of claim 1 teaches gene expression using a jet injector, and the "steps" of other protocols, as designated in claim 2, are generally known in the art, but not with respect to the use of a jet injector. It is the use of the jet injector to carry forth the known "steps" that renders the instantly claimed invention novel without creating the alleged ambiguity. And thus, a person of ordinary skill would know what is meant by "the steps", as recited in claim 2.

In view of the foregoing, Applicants submit that claims 1-12 and 19-21 are definite. Accordingly, Applicants respectfully request withdrawal of the rejection under Section 112, second paragraph.

In re Appln. of Furth et al.
Application No. 10/037,616

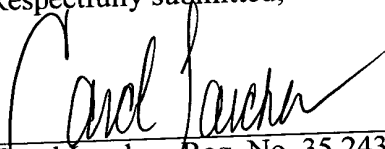
Discussion of the Nonstatutory Obviousness-Type Double Patenting Rejection

Claims 1-12 and 19-21 have been rejected under the judicially created doctrine of nonstatutory obviousness-type double patenting over claim 12 of U.S. Patent No. 5,998,382 (the '382 patent). With regard to the obviousness-type double patenting rejection, the Office's attention is drawn to the enclosed Terminal Disclaimer Under 37 C.F.R. § 1.321(b), which is based on the '382 patent. The enclosed Terminal Disclaimer is believed to render moot the obviousness-type double patenting rejection.

Conclusion

The application is considered to be in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



Carol Larcher, Reg. No. 35,243
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson
Chicago, Illinois 60601-6780
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

Date: March 6, 2003